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108TH CONGRESS
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S. 720

[Report No. 108–196]

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2003

Mr. JEFFORDS (for himself, Mr. FRIST, Mr. BREAUX, Mr. GREGG, Mr. ENZI, Mr. HAGEL, and Mr. SMITH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 17, 2003

Reported by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Safety and Quality Improvement Act''.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1999, the Institute of Medicine released a report entitled To Err is Human that described medical errors as the eighth leading cause of death in the United States, with as many as 98,000 people dying as a result of medical errors each year.

(2) To address these deaths and injuries due to medical errors, the health care system must identify and learn from such errors so that systems of care can be improved.

(3) In their report, the Institute of Medicine called on Congress to provide legal protections with respect to information reported for the purposes of quality improvement and patient safety.

(4) The Health, Education, Labor, and Pensions Committee of the Senate held 4 hearings in the 106th Congress and 1 hearing in the 107th Congress on patient safety where experts in the field supported the recommendation of the Institute of Medicine for congressional action.

(5) Myriad public and private patient safety initiatives have begun. The Quality Interagency Coordination Taskforce has recommended steps to improve patient safety that may be taken by each Federal agency involved in health care and activities relating to these steps are ongoing.

(6) The research on patient safety unequivocally calls for a learning environment, rather than a punitive environment, in order to improve patient safety.

(7) Voluntary data gathering systems are more supportive than mandatory systems in creating the learning environment referred to in paragraph (5) as stated in the Institute of Medicine's report.

(8) Promising patient safety reporting systems have been established throughout the United States and the best ways to structure and use these systems are currently being determined, largely through projects funded by the Agency for Healthcare Research and Quality.

(9) The Department of Health and Human Services has initiated several patient safety projects. The Joint Commission on Accreditation of Healthcare Organizations issued a patient safety standard that went into effect on July 1, 2001, and

the peer review organizations are conducting ongoing studies of clinical performance measurement of care delivered to beneficiaries under the medicare program under title XVIII of the Social Security Act.

(10) Many organizations currently collecting patient safety data have expressed a need for legal protections that will allow them to review protected information so that they may collaborate in the development and implementation of patient safety improvement strategies. Currently, the State peer review protections provide inadequate conditions to allow the sharing of information to promote patient safety.

(11) In 2001, the Institute of Medicine released a report entitled Crossing the Quality Chasm that found that the United States health care system does not consistently deliver high quality care to patients.

(b) PURPOSES.—It is the purpose of this Act to—

(1) encourage a culture of safety and quality in the United States health care system by providing for legal protection of information reported voluntarily for the purposes of quality improvement and patient safety; and

(2) ensure accountability by raising standards and expectations for continuous quality improvements in patient safety through the actions of the Secretary of Health and Human Services.

SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) in section 912(c), by inserting ", in accordance with part C," after "The Director shall";

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(4) in section 938(1) (as so redesignated), by striking "921" and inserting "931"; and

(5) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) NON-IDENTIFIABLE INFORMATION.—The term 'non-identifiable information' means information that is presented in a form and manner that prevents the identification of any provider, patient, and the reporter of patient safety data.

"(2) PATIENT SAFETY DATA.—The term 'patient safety data' means—

‘‘(A) any data, reports, records, memoranda, analyses, deliberative work, statements, root cause analyses, or quality improvement processes that could result in improved patient safety or health care quality, that are—

‘‘(i) collected or developed by a provider for the purpose of reporting to a patient safety organization;

‘‘(ii) reported to a patient safety organization for patient safety or quality improvement processes;

‘‘(iii) requested by a patient safety organization (including the contents of such request);

‘‘(iv) reported to a provider by a patient safety organization;

‘‘(v) collected or developed by a patient safety organization; or

‘‘(vi) reported among patient safety organizations, after obtaining authorization; or

‘‘(B) information related to corrective actions taken in response to patient safety data; for the purpose of improving patient safety, health care quality, or health care outcomes.

"(3) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization or component thereof that performs the following activities (which are deemed to be necessary for the proper management and administration of such organization or component thereof):

"(A) The conduct, as its primary activity, of efforts to improve patient safety and the quality of health care delivery.

"(B) The collection and analysis of patient safety data that are voluntarily submitted by a provider.

"(C) The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

"(D) The utilization of patient safety data to carry out activities under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

"(E) The maintenance of confidentiality with respect to individually identifiable health information.

"(F) The provision of appropriate security measures with respect to patient safety data.

"(G) The certification to the Agency that the patient safety organization satisfies the criteria of this paragraph for the period in which the organization is carrying out such duties.

"(4) PROVIDER.—The term 'provider' means—

"(A) a provider of services (as defined in section 1861(u) of the Social Security Act) and a person furnishing any medical or other health care services (as defined in section 1861(s)(1) and (2) of such Act) through, or under the authority of, such a provider of services;

"(B) a physician (as defined in section 1861(r) of such Act);

"(C) any other person, including a pharmacist, who is engaged in the delivery of medical or other health services (as defined in section 1861(s)(1) and (2) of such Act) in a State and who is required by State law or regulation to be licensed or certified by the State to en-

gage in the delivery of such services in the State;

''(D) a renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavioral health residential treatment facility, or clinical laboratory; or

''(E) any other person or entity specified in regulations by the Secretary after public notice and comment.

''SEC. 922. CONFIDENTIALITY AND PEER REVIEW PROTECTIONS.

''(a) IN GENERAL.—Notwithstanding any other provision of law, and subject to this section, patient safety data shall be privileged and confidential.

''(b) SCOPE OF PRIVILEGE.—Subject to the provisions of subsection (c), patient safety data to which subsection (a) applies shall not be—

''(1) subject to a civil, criminal, or administrative subpoena;

''(2) subject to discovery in connection with a civil, criminal, or administrative proceeding;

''(3) disclosed pursuant to section 552 of title 5, United States Code (commonly known as the

Freedom of Information Act) or any other similar Federal or State law;

''(4) admitted as evidence or otherwise disclosed in any civil, criminal, or administrative proceeding; or

''(5) utilized in an adverse employment action or in the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual, that is based on such individual's participation in the development, collection, reporting, or storage of patient safety data in accordance with this part.

''(c) DISCLOSURE REQUIREMENTS.—Nothing in this section shall be construed to prohibit one or more of the following disclosures (which are deemed to be necessary for the proper management and administration of the patient safety organization):

''(1) Disclosures by a provider in complying with authorized requests for the provision of information to which subsection (a) applies (such as a patient's medical record or other relevant information) that is in the control of such a provider and that has been developed, maintained, or exists separately from the process by which the provider col-

lects or develops information for reporting to a patient safety organization.

''(2) Disclosures by a provider or patient safety organization of patient safety data as part of a disciplinary proceeding relating to a provider, or a criminal proceeding, if such a disclosure of such patient safety data is—

''(A) material to the proceeding;

''(B) within the public interest; and

''(C) not available from any other source.

''(3) Disclosures by a provider or patient safety organization of relevant information to the Food and Drug Administration, or to a person that is subject to the jurisdiction of such Administration, with respect to an Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of such Administration-regulated product or activity, subject to section 520(e) of the Federal Food, Drug, and Cosmetic Act.

''(4) Disclosures by a provider or patient safety organization of information to which subsection (a) applies to carry out activities described in paragraph (2)(A) (i) through (vi) or (3) of section 921.

''(d) TRANSFER OF INFORMATION.—The transfer of any patient safety data by a provider to a patient safety organization shall not be treated as a waiver of any privilege or protection established under this part or established under State law.

''(e) PENALTY.—Except as provided in subsection (c) and as otherwise provided for in this section, it shall be unlawful for any person to disclose any patient safety data described in subsection (a). Any person violating the provisions of this section shall, upon conviction, be fined in accordance with section 934(d).

''(f) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to limit other privileges that are available under Federal or State laws that provide greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this section.

''(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) or any regulation promulgated under such section.

''SEC. 923. NATIONAL DATABASE.

''(a) AUTHORITY.—

''(1) IN GENERAL.—In conducting activities under this part, the Secretary may provide for the establishment and maintenance of a database to receive relevant non-identifiable patient safety data, or may designate entities to collect relevant non-identifiable patient safety data, that is voluntarily reported by patient safety organizations upon the request of the Secretary.

''(2) USE OF DATA.—Data reported to any database established or designated under paragraph (1) shall be used to analyze regional variations and national statistics related to patient safety and health care quality. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2).

''(b) STANDARDS.—In developing or designating a database under subsection (a)(1), the Secretary may determine common formats for the voluntary reporting of non-identifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

''(c) CONFIDENTIALITY.—Any non-identifiable patient safety data that is transferred to the database under this section shall be privileged and confidential.

''SEC. 924. TECHNICAL ASSISTANCE.

''The Secretary, acting through the Director, may provide technical assistance to patient safety organizations. Such assistance shall include annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

''SEC. 925. PROMOTING THE INTEGRATION OF HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

''(a) DEVELOPMENT.—Not later than 36 months after the date of enactment of the Patient Safety and Quality Improvement Act, the Secretary shall develop or adopt voluntary national standards that promote the integration of health care information technology systems.

''(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

''(c) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

''SEC. 926. AUTHORIZATION OF APPROPRIATIONS.

''There is authorized to be appropriated such sums as may be necessary to carry out this part.''.

SEC. 4. STUDIES AND REPORTS.

(a) MEDICAL TECHNOLOGIES AND THERAPIES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with an appropriate research organization for the conduct of a study to assess the impact of medical technologies and therapies on patient safety, patient benefit, health care quality, and the costs of care as well as productivity growth. Such study shall determine—

(A) the extent to which the current health care system's use of labor versus the use of technology has contributed to increases in the share of the gross domestic product that is devoted to health care and the impact of medical technologies and therapies on such increases;

(B) the extent to which early and appropriate introduction and integration of innovative medical technologies and therapies may affect the overall productivity and quality of the health care delivery systems of the United States; and

(C) the relationship of such medical technologies and therapies to patient safety, patient benefit, health care quality, and cost of care.

(2) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of

~~Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing the results of the study conducted under paragraph (1).~~

~~(b) STATE LAWS RELATING TO PATIENT SAFETY PEER REVIEW SYSTEMS.—~~

~~(1) SURVEY.—The Attorney General shall conduct a survey of State laws that relate to patient safety data peer review systems, including laws that establish an evidentiary privilege applicable to data developed by such systems, and shall review the manner in which such laws have been interpreted by the courts.~~

~~(2) REPORT.—Not later than 9 months after the date of enactment of this Act, the Attorney General shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of the survey conducted under paragraph (1).~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Patient Safety and Quality Improvement Act of 2003".

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) In 1999, the Institute of Medicine released a report entitled To Err is Human that described medical errors as the eighth leading cause of death in the United States, with as many as 98,000 people dying as a result of medical errors each year.

(2) To address these deaths and injuries due to medical errors, the health care system must identify and learn from such errors so that systems of care can be improved.

(3) In their report, the Institute of Medicine called on Congress to provide legal protections with respect to information reported for the purposes of quality improvement and patient safety.

(4) The Health, Education, Labor, and Pensions Committee of the Senate held 4 hearings in the 106th Congress and 1 hearing in the 107th Congress on patient safety where experts in the field supported the recommendation of the Institute of Medicine for congressional action.

(5) Myriad public and private patient safety initiatives have begun. The Quality Interagency Coordination Taskforce has recommended steps to improve patient safety that may be taken by each Fed-

eral agency involved in health care and activities relating to these steps are ongoing.

(6) The research on patient safety unequivocally calls for a learning environment, rather than a punitive environment, in order to improve patient safety.

(7) Voluntary data gathering systems are more supportive than mandatory systems in creating the learning environment referred to in paragraph (6) as stated in the Institute of Medicine's report.

(8) Promising patient safety reporting systems have been established throughout the United States and the best ways to structure and use these systems are currently being determined, largely through projects funded by the Agency for Healthcare Research and Quality.

(9) Many organizations currently collecting patient safety data have expressed a need for legal protections that will allow them to review protected information and collaborate in the development and implementation of patient safety improvement strategies. Currently, the State peer review protections are inadequate to allow the sharing of information to promote patient safety.

(b) PURPOSES.—It is the purpose of this Act to—

(1) encourage a culture of safety and quality in the United States health care system by providing for legal protection of information reported voluntarily for the purposes of quality improvement and patient safety; and

(2) ensure accountability by raising standards and expectations for continuous quality improvements in patient safety.

SEC. 3. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) in section 912(c), by inserting ", in accordance with part C," after "The Director shall";

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(4) in 934(d) (as so redesignated), by striking the second sentence and inserting the following: "Penalties provided for under this section shall be imposed and collected by the Secretary using the administrative and procedural processes used to impose and collect civil money penalties under section 1128A of the Social Security Act (other than subsections (a) and (b), the second sentence of subsection (f), and subsections (i), (m), and (n)), unless the Secretary deter-

mines that a modification of procedures would be more suitable or reasonable to carry out this subsection and provides for such modification by regulation.";

(5) in section 938(1) (as so redesignated), by striking "921" and inserting "931"; and

(6) by inserting after part B the following:

"PART C—PATIENT SAFETY IMPROVEMENT

"SEC. 921. DEFINITIONS.

"In this part:

"(1) NON-IDENTIFIABLE INFORMATION.—

"(A) IN GENERAL.—The term 'non-identifiable information' means information that is presented in a form and manner that prevents the identification of a provider, a patient, or a reporter of patient safety data.

"(B) IDENTIFIABILITY OF PATIENT.—For purposes of subparagraph (A), the term 'presented in a form and manner that prevents the identification of a patient' means, with respect to information that has been subject to rules promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), that the information has been de-identified so that it is

no longer individually identifiable health information as defined in such rules.

"(2) PATIENT SAFETY DATA.—

"(A) IN GENERAL.—The term 'patient safety data' means—

"(i) any data, reports, records, memoranda, analyses (such as root cause analyses), or statements that could result in improved patient safety or health care quality or health care outcomes, that are—

"(I) collected or developed by a provider for reporting to a patient safety organization, provided that they are reported to the patient safety organization within a reasonable period of time;

"(II) requested by a patient safety organization (including the contents of such request);

"(III) reported to a provider by a patient safety organization; or

"(IV) collected from a provider or patient safety organization or developed by a patient safety organization; or

"(ii) any deliberative work or process or oral communications with respect to any patient safety data described in clause (i).

"(B) LIMITATION.—The term 'patient safety data' shall not include information (including a patient's medical record) that is collected or developed separately from and that exists separately from patient safety data. Such separate information or a copy thereof submitted to a patient safety organization shall not itself be considered as patient safety data.

"(3) PATIENT SAFETY ORGANIZATION.—The term 'patient safety organization' means a private or public organization or component thereof that performs all of the following activities (which are deemed to be necessary for the proper management and administration of such organization or component thereof), and that is currently listed by the Secretary as a patient safety organization pursuant to section 924(c):

"(A) The conduct, as its primary activity, of efforts to improve patient safety and the quality of health care delivery.

"(B) The collection and analysis of patient safety data that are submitted by more than one provider.

"(C) The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

"(D) The utilization of patient safety data for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

"(E) The maintenance of a process to preserve confidentiality with respect to the information that is not non-identifiable.

"(F) The provision of appropriate security measures with respect to patient safety data.

"(G) The submittal to the Secretary of a certification pursuant to section 924.

"(4) PROVIDER.—The term 'provider' means—

"(A) a person licensed or otherwise authorized under State law to provide health care services, including—

"(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center,

pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

"(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

"(B) any other person specified in regulations promulgated by the Secretary.

"SEC. 922. PRIVILEGE AND CONFIDENTIALITY PROTECTIONS.

"(a) PRIVILEGE.—Notwithstanding any other provision of Federal, State, or local law, patient safety data shall be privileged and, subject to the provisions of subsection (c), shall not be—

"(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena;

"(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding;

"(3) disclosed pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

"(4) admitted as evidence or otherwise disclosed in any Federal, State, or local civil, criminal, or administrative proceeding; or

"(5) utilized in a disciplinary proceeding against a provider.

"(b) CONFIDENTIALITY.—Notwithstanding any other provision of Federal, State, or local law, and subject to the provisions of subsections (c) and (d), patient safety data shall be confidential and shall not be disclosed.

"(c) EXCEPTIONS TO PRIVILEGE AND CONFIDENTIALITY.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

"(1) Disclosure by a provider or patient safety organization of relevant patient safety data for use in a criminal proceeding only after a court makes an in camera determination that such patient safety data contains evidence of an intentional act to directly harm the patient.

"(2) Voluntary disclosure by a provider or patient safety organization of information to the Food and Drug Administration, or to a person that is sub-

ject to the jurisdiction of the Food and Drug Administration, with respect to a Food and Drug Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effectiveness of a Food and Drug Administration-regulated product or activity or a Food and Drug Administration proceeding.

"(3) Voluntary disclosure of non-identifiable patient safety data by a provider or a patient safety organization.

"(4) Voluntary disclosure by a provider of patient safety data to the Centers for Disease Control and Prevention for public health surveillance, investigation, or other public health activities.

"(d) PROTECTED DISCLOSURE AND USE OF INFORMATION.—Nothing in this section shall be construed to prohibit one or more of the following uses or disclosures:

"(1) Disclosure by a provider or patient safety organization of information to which subsections (a) or (b) applies to carry out activities described in paragraph (2) or (3) of section 921.

"(2) Use or disclosure by a provider or patient safety organization of patient safety data in connection with providing treatment, improving patient safety, health care quality or administrative effi-

ciency, or any other customary activity of the provider or in obtaining payment.

"(3) Disclosure of patient safety data among patient safety organizations.

"(4) Disclosure of patient safety data by a provider or patient safety organization to grantees or contractors carrying out patient safety research, evaluation, or demonstration projects authorized by the Director.

"(5) Disclosure of patient safety data by a provider to an accrediting body that accredits that provider.

"(e) CONTINUED PROTECTION OF INFORMATION.—Patient safety data used or disclosed in accordance with subsection (d) shall continue to be privileged and confidential in accordance with subsections (a) and (b) and shall not be disclosed—

"(1) by an entity that possessed such information before such use or disclosure; or

"(2) by an entity to which the information was disclosed;

unless such additional disclosure is permitted under subsection (d).

"(f) LIMITATION ON ACTIONS.—

"(1) PATIENT SAFETY ORGANIZATIONS.—Except as provided in subsection (c), no action may be brought or process served against a patient safety organization to compel disclosure of information collected or developed under this part whether or not such information is patient safety data.

"(2) PROVIDERS.—An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety data in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

"(g) DISCLOSURE OR USE OF INFORMATION.—

"(1) IN GENERAL.—Except with respect to the specific patient safety data that is used or disclosed, the disclosure or use of any patient safety data in accordance with subsection (c) or (d) shall not be treated as a waiver of any privilege or protection established under this part.

"(2) INADVERTENT DISCLOSURE OR USE.—The inadvertent disclosure or use of patient safety data shall not waive any privilege or protection established under this part with respect to such data.

"(h) REPORTER PROTECTION.—

"(1) IN GENERAL.—A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

"(A) to the provider with the intention of having the information reported to a patient safety organization; or

"(B) directly to a patient safety organization.

"(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

"(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

"(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

"(i) ENFORCEMENT.—

"(1) PROHIBITION.—Except as provided in subsections (c) and (d) and as otherwise provided for in this section, it shall be unlawful for any person to

negligently or intentionally disclose any patient safety data described in subsection (a) and any such person shall, upon adjudication, be assessed in accordance with section 934(d).

"(2) RELATION TO HIPAA.—The penalty provided for under paragraph (1) shall not apply if the defendant would otherwise be subject to a penalty under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) or under section 1176 of the Social Security Act (42 U.S.C. 1320d–5) for the same disclosure.

"(3) EQUITABLE RELIEF.—Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (h) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

"(4) ACTIONS AGAINST STATE EMPLOYEES.—Notwithstanding subsection (a), with respect to a State employer, the privilege described in such subsection shall not apply to such employer unless the employer consents, in advance, to be subject to a civil action under paragraph (3).

"(j) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to—

"(1) limit other privileges that are available under Federal, State, or local laws that provide greater confidentiality protections or privileges than the privilege and confidentiality protections provided for in this section;

"(2) limit, alter, or affect the requirements of Federal, State, or local law pertaining to patient-related data that is not privileged or confidential under this section;

"(3) alter or affect the implementation of any provision of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033), section 1176 of the Social Security Act (42 U.S.C. 1320d–5), or any regulation promulgated under such sections;

"(4) limit the authority of any provider, patient safety organization, or other person to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with subsection (c) or (d); and

"(5) prohibit a provider from reporting crime to law enforcement authorities.

"SEC. 923. PATIENT SAFETY NETWORK OF DATABASES.

"(a) IN GENERAL.—The Secretary shall maintain a patient safety network of databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other persons. The network of databases shall have the capacity to accept, aggregate, and analyze nonidentifiable patient safety data voluntarily reported by patient safety organizations, providers, or other persons.

"(b) NETWORK OF DATABASE STANDARDS.—The Secretary may determine common formats for the reporting to the patient safety network of databases maintained under subsection (a) of nonidentifiable patient safety data, including necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

"SEC. 924. PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING.

"(a) CERTIFICATION.—

"(1) INITIAL CERTIFICATION.—Except as provided in paragraph (2), an entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity intends

to perform the activities described in subparagraphs (A) through (F) of section 921(3).

"(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—An entity that seeks to be a patient safety organization may—

"(A) submit an initial certification that it intends to perform the activities described in subparagraph (A) through (F) of section 921(3) other than the activities described in subparagraph (B) of such section; and

"(B) within 2 years of submitting the initial certification under subparagraph (A), submit a supplemental certification that it performs the activities described in section 921(3)(B).

"(3) EXPIRATION AND RENEWAL.—

"(A) EXPIRATION.—An initial certification under paragraph (1) or (2)(A) shall expire on the date that is 3 years after it is submitted.

"(B) RENEWAL.—

"(i) IN GENERAL.—An entity that seeks to remain a patient safety organization after the expiration of an initial certification under paragraph (1) or (2)(A) shall, within the 3-year period described in subparagraph (A), submit a renewal certifi-

cation to the Secretary that the entity satisfies the criteria described in subparagraph (A) through (F) of section 921(3).

"(ii) TERM OF RENEWAL.—A renewal certification under clause (i) shall expire on the date that is 3 years after that date on which it is submitted, and may be renewed in the same manner as an initial certification.

"(b) ACCEPTANCE OF CERTIFICATION.—Upon the submission by an organization of an initial certification pursuant to subsection (a)(1) or (a)(2)(A), a supplemental certification pursuant to subsection (a)(2)(B), or a renewal certification pursuant to subsection (a)(3)(B), the Secretary shall review such certification and—

"(1) if such certification meets the requirements of subsection (a)(1) or (a)(2)(A), (a)(2)(B), or (a)(3)(B), as applicable, the Secretary shall notify the organization that such certification is accepted; or

"(2) if such certification does not meet such requirements, as applicable, the Secretary shall notify the organization that such certification is not accepted and the reasons therefore.

"(c) LISTING.—

"(1) IN GENERAL.—Except as otherwise provided in this subsection, the Secretary shall compile and maintain a current listing of patient safety organizations with respect to which the Secretary has accepted a certification pursuant to subsection (b).

"(2) REMOVAL FROM LISTING.—The Secretary shall remove from the listing under paragraph (1)—

"(A) an entity with respect to which the Secretary has accepted an initial certification pursuant to subsection (a)(2)(A) and which does not submit a supplemental certification pursuant to subsection (a)(2)(B) that is accepted by the Secretary;

"(B) an entity whose certification expires and which does not submit a renewal application that is accepted by the Secretary; and

"(C) an entity with respect to which the Secretary revokes the Secretary's acceptance of the entity's certification, pursuant to subsection (d).

"(d) REVOCATION OF ACCEPTANCE.—

"(1) IN GENERAL.—Except as provided in paragraph (2), if the Secretary determines that a patient safety organization does not perform any activity described in subparagraph (A) through (F) of section

921(3), the Secretary may, after notice and an opportunity for a hearing, revoke the Secretary's acceptance of the certification of such organization.

"(2) DELAYED CERTIFICATION OF COLLECTION FROM MORE THAN ONE PROVIDER.—A revocation under paragraph (1) may not be based on a determination that the organization does not perform the activity described in section 921(3)(B) if—

"(A) the listing of the organization is based on its submittal of an initial certification under subsection (a)(2)(A);

"(B) the organization has not submitted a supplemental certification under subsection (a)(2)(B); and

"(C) the 2-year period described in subsection (a)(2)(B) has not expired.

"(e) NOTIFICATION OF REVOCATION OR REMOVAL FROM LISTING.—

"(1) SUPPLYING CONFIRMATION OF NOTIFICATION TO PROVIDERS.—Within 15 days of a revocation under subsection (d)(1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety data is col-

lected or analyzed by the organization of such revocation.

"(2) PUBLICATION.—Upon the revocation of an acceptance of an organization's certification under subsection (d)(1), or upon the removal of an organization from the listing under subsection (c)(2), the Secretary shall publish notice of the revocation or removal in the Federal Register.

"(f) STATUS OF DATA AFTER REMOVAL FROM LISTING.—

"(1) NEW DATA.—With respect to the privilege and confidentiality protections described in section 922, data submitted to an organization within 30 days after the organization is removed from the listing under subsection (c)(2) shall have the same status as data submitted while the organization was still listed.

"(2) PROTECTION TO CONTINUE TO APPLY.—If the privilege and confidentiality protections described in section 922 applied to data while an organization was listed, or during the 30-day period described in paragraph (1), such protections shall continue to apply to such data after the organization is removed from the listing under subsection (c)(2).

"(g) DISPOSITION OF DATA.—If the Secretary revokes the acceptance of an organization's certification under subsection (d)(1) and removes the organization from the listing as provided for in subsection (c)(2), with respect to the patient safety data that the organization received from providers, the organization shall—

"(1) with the approval of the provider and another patient safety organization, transfer such data to such other organization;

"(2) return such data to the provider of that patient safety data; or

"(3) if returning such data to the provider is not practicable, destroy such data.

"SEC. 925. TECHNICAL ASSISTANCE.

"The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

"SEC. 926. PROMOTING THE INTEROPERABILITY OF HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS.

"(a) DEVELOPMENT.—Not later than 36 months after the date of enactment of the Patient Safety and Quality Improvement Act of 2003, the Secretary shall develop or

adopt voluntary national standards that promote the electronic exchange of health care information.

"(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

"(c) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

"SEC. 927. AUTHORIZATION OF APPROPRIATIONS.

"There is authorized to be appropriated such sums as may be necessary to carry out this part.".

SEC. 4. STUDIES AND REPORTS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract (based upon a competitive contracting process) with an appropriate research organization for the conduct of a study to assess the impact of medical technologies and therapies on patient safety, patient benefit, health care quality, and the costs of care as well as productivity growth. Such study shall examine—

(1) the extent to which factors, such as the use of labor and technological advances, have contributed to increases in the share of the gross domestic product that is devoted to health care and the impact of medical technologies and therapies on such increases;

(2) the extent to which early and appropriate introduction and integration of innovative medical technologies and therapies may affect the overall productivity and quality of the health care delivery systems of the United States; and

(3) the relationship of such medical technologies and therapies to patient safety, patient benefit, health care quality, and cost of care.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing the results of the study conducted under subsection (a).

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108TH CONGRESS
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S. 720

[Report No. 108–196]

A BILL

To amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect patient safety.

NOVEMBER 17, 2003

Reported with an amendment